APR 2 0 2001

VI. Safety and Effectiveness Summary

K010341
p.1/2

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic PS Medical 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1770 Fax: (805) 968-5617
Contact Person:	Janet McAuley
Date:	January 30, 2001
Trade or Proprietary Name:	Medtronic PS Medical MurphyScope Endoscope and Light Cables
Common usual or Classification Name:	Neurological Endoscope (882.1480)
Predicate Device Identification:	Clarus MurphyScope Endoscope (K926048)

Description: The Medtronic PS Medical, MurphyScope Endoscope is manufactured of stainless steel with a molded plastic handle. The working length of each scope consists of a rigid or malleable (able to be bent and shaped) stainless sheath.

Intended Use: The Medtronic PS Medical MurphyScope Endoscope is designed for visual inspection of nerves and surrounding tissue during intra-operative, general and intracranial neurological surgical procedures where cerebrospinal fluid may be contacted. These procedures may include visualization of the subarachnoid, spine epidural, spine-intradural, or ventricular space for conditions such as Acoustic neuroma, lateral herniation of lumbar discs, syringomelia, and hydrocephalus.

The Medtronic PS Medical Light Cables allow for attachment of Medtronic PS Medical neuroendoscopes to a variety of light sources.

Intended Use of predicate device: "The Clarus MurphyScope Endoscope is designed for visual inspection of nerves and surrounding tissue during intra-operative, general and intracranial neurological surgical procedures where cerebrospinal fluid may be contacted."

"The Clarus Light Cables allow for attachment of Medtronic PS Medical neuroendoscopes to a variety of light sources"

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the MurphyScope Endoscope and Light Cables are substantially equivalent to those of the predicate device. Based upon the summary above, Medtronic PS Medical determines substantial equivalence, safety, and efficacy of the MurphyScope Endoscope and Light Cables based upon the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

Ms. Janet McAuley
Regulatory Specialist
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K010341
Trade/Device Name: MurphyScope Endoscope and Light Cables
Regulation Number: 882.1480
Regulatory Class: II
Product Code: GWG
Dated: February 3, 2001
Received: February 5, 2001

Dear Ms. McAuley

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: MurphyScope Endoscope and Light Cables

Abbreviated 510(k) Number (if known): K 010341

Indications for Use:

The Medtronic PS Medical MurphyScope Endoscope is designed for visual inspection of nerves and surrounding tissue during intra-operative, general and intracranial neurological surgical procedures where cerebrospinal fluid may be contacted. These procedures may include visualization of the subarachnoid, spine-epidural, spine-intradural, or ventricular space for conditions such as Acoustic neuroma, lateral herniation of lumbar discs, syringomelia, and hydrocephalus.

The Medtronic PS Medical Light Cables allow for attachment of Medtronic PS Medical neuroendoscopes to a variety of light sources.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: ✓
(Per 21 CFR 801.109)

(optional format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010341